INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.
100 N. Senate Avenue • Indianapolis, IN 46204
(800) 451-6027 • (317) 232-8603 • www.idem.IN.gov
Eric J. Holcomb
Governor
Bruno L. Pigott
Commissioner

To: Interested Parties

Date: March 6, 2020

From: Jenny Acker, Chief
Permits Branch
Office of Air Quality

Source Name: Cook Incorporated

Permit Level: FESOP Administrative Amendment

Permit Number: 105-42357-00030

Source Location: 6330 North Matthews Drive, Ellettsville, IN 47429

Type of Action Taken: Changes that are administrative in nature

Notice of Decision: Approval

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the matter referenced above. Pursuant to 326 IAC 2, this approval was effective immediately upon submittal of the application.

The final decision is available on the IDEM website at: http://www.in.gov/apps/idem/caats/
To view the document, choose Search Option **by Permit Number**, then enter permit 42357.

The final decision is also available via IDEM's Virtual File Cabinet (VFC). Please go to: http://www.IN.idem/gov and enter VFC in the search box. You will then have the option to search for permit documents using a variety of criteria.

(continues on next page)

If you would like to request a paper copy of the permit document, please contact IDEM's Office of Records Management:

IDEM - Office of Records Management
Indiana Government Center North, Room 1207
100 North Senate Avenue
Indianapolis, IN 46204
Phone: (317) 232-8667
Fax: (317) 233-6647
Email: IDEMFILEROOM@idem.in.gov

If you wish to challenge this decision, IC 4-21.5-3-7 requires that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room N103, Indianapolis, IN 46204, **within eighteen (18) calendar days from the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

(1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
(2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
(3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

(1) the name and address of the person making the request;
(2) the interest of the person making the request;
(3) identification of any persons represented by the person making the request;
(4) the reasons, with particularity, for the request;
(5) the issues, with particularity, proposed for considerations at any hearing; and
(6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

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Eric J. Holcomb
Governor
Bruno L. Pigott
Commissioner

March 6, 2020

Mr. Shawn Adams
Cook Incorprated
P.O. Box 489
Bloomington, IN 47402-0489

Re: 105-42357-00030
Administrative Amendment to
FESOP Renewal No. F105-40744-00030

Dear Mr. Adams:

Cook Incorporated was issued a Federally Enforceable State Operating Permit (FESOP) Renewal No. 105-40744-00030 on August 30, 2019 for a stationary medical device manufacturing and sterilization operation located at 6300 North Matthews Drive, Ellettsville, Indiana. On December 23, 2019, the Office of Air Quality (OAQ) received an application from the source requesting to add eighteen (18) dry bed reactors to the permit through Voluntary Emissions Reduction for VOC and HAPs for internal quality purposes.

Pursuant to the provisions of 326 IAC 2-8-10(a), the permit is hereby administratively amended as described in the attached Technical Support Document.

All other conditions of the permit shall remain unchanged and in effect.

All other conditions of the permit shall remain unchanged and in effect. Please find attached the entire FESOP as amended. The permit references the below listed attachment(s).

Attachment A: 40 CFR 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities
Attachment B: 40 CFR 63, Subpart ZZZZ, Stationary Reciprocating Internal Combustion Engines

Previously issued approvals for this source containing these attachments are available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/.

Previously issued approvals for this source are also available via IDEM's Virtual File Cabinet (VFC). Please go to: http://www.in.gov/idem/ and enter VFC in the search box. You will then have the option to search for permit documents using a variety of criteria.

Federal rules under Title 40 of United States Code of Federal Regulations may also be found on the U.S. Government Printing Office's Electronic Code of Federal Regulations (eCFR) website, located on the Internet at: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40tab_02.tpl.

A copy of the permit is available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/. A copy of the permit is also available via IDEM's Virtual File Cabinet (VFC). Please go to: http://www.in.gov/idem/ and enter VFC in the search box. You will then have the option to search for permit documents using a variety of criteria. For additional information about air permits and how the public and interested parties can participate, refer to the IDEM Air Permits page on the Internet at: http://www.in.gov/idem/airquality/2356.htm; and the Citizens' Guide to IDEM on the Internet at: http://www.in.gov/idem/6900.htm.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5.

If you have any questions regarding this matter, please contact Jared Karban, Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana 46204-2251, or by telephone at (317) 233-4230 or (800) 451-6027, and ask for Jared Karban or (317) 233-4230.

Sincerely,

Ghassan Shalabi, Section Chief
Permits Branch
Office of Air Quality

Attachment(s): Updated Permit and Technical Support Document

cc: File - Monroe County
Monroe County Health Department
U.S. EPA, Region 5
Compliance and Enforcement Branch
IDEM Southeast Regional Office

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Eric J. Holcomb
Governor

Bruno L. Pigott
Commissioner

Federally Enforceable State Operating Permit Renewal
OFFICE OF AIR QUALITY

Cook Incorporated
6330 North Matthews Drive
Ellettsville, Indiana 47429

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-8 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Indiana statutes from IC 13 and rules from 326 IAC, quoted in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a FESOP under 326 IAC 2-8.

Operation Permit No.: F 105-40744-00030 Master Agency Interest ID: 11774	
Original issued by: Josiah K. Balogun, Section Chief Permits Branch Office of Air Quality	Issuance Date: August 30, 2019 Expiration Date: August 30, 2029

Administrative Amendment No.: 105-42357-00030	
Issued by:  Ghassan Shalabi, Section Chief Permits Branch Office of Air Quality	Issuance Date: March 6, 2020 Expiration Date: August 30, 2029

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Attachment B: Stationary Reciprocating Internal Combustion Engines NESHAP [40 CFR 63, Subpart ZZZZ]

SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-8-3(b)]

The Permittee owns and operates a stationary medical device manufacturing and sterilization operation.

Source Address:	6330 North Matthews Drive, Ellettsville, Indiana 47429
General Source Phone Number:	(812) 339-2235
SIC Code:	3841 (Surgical and Medical Instruments and Apparatus)
County Location:	Monroe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Federally Enforceable State Operating Permit Program Minor Source, under PSD Minor Source, Section 112 of the Clean Air Act Not 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-8-3(c)(3)]

This stationary source consists of the following emission units and pollution control devices:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, where:

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non-regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) During aeration cycle, zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01.

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(d) Eight (8) Facility Room Vents, identified as Sterilization Room Vents (SRV) SRV1 through SRV7 and the ethylene oxide dispensing room vents, exhausting through fifteen (15) voluntary non-regenerable dry bed units exhausting through five (5) independent stacks.

(1) SRV1 and SRV2 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RSV01.

(2) SRV3 and SRV4 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV02.

(3) SRV5 and SRV6 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV03.

(4) EO Dispensing Room Vent exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV04.

(5) SRV7 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV05.

(e) Miscellaneous cleaning with isopropyl alcohol (IPA), methanol and ethanol.

(f) One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and constructed in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

[The diesel-fired emergency generator, identified as Unit #1 is an existing affected facility under 40 CFR 63, Subpart ZZZZ.]

(g) One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and constructed in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

[The diesel-fired emergency generator, identified as Unit #2 is an existing affected facility under 40 CFR 63, Subpart ZZZZ.]

A.3 Insignificant Activities [326 IAC 2-7-1(21)][326 IAC 2-8-3(c)(3)(I)]

This stationary source also includes the following insignificant activities:

(a) Slipcoating operations consisting of the mixing and coating of medical devices with solids mixed with isopropyl alcohol and water, isopropyl alcohol and methylene chloride, or ethanol to create a hydrophilic surface which is cured by ultraviolet light.

(b) The following storage containers:

(1) nine (9) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (3,600 pounds total). These are portable cylinders that will be connected to the sterilization process.

(2) nine (9) 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide on standby for connection to the sterilization process as cylinders are emptied.

(3) up to four (4) additional 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide to be stored on site.

(c) Three (3) liquor storage tanks, identified as Tanks A, B, and C, each with a working storage capacity of 5,870 gallons, all venting to the wet acid pre-scrubber, exhausting through one (1) stack, identified as HV01.

(d) Gluing, heat forming, tapering, marking and printing operations associated with manufacturing activities and product assembly, exhausting through building exhausts and one (1) stack, identified as S10.

(e) Natural gas fired combustion sources including the following:

Emission units	Construction Date	ID	Heat Input Capacity (MMBtu/hr)	
NG boiler	2003	C241-F	2.1349	uncontrolled, exhausting to stack
NG boiler	2003	C242-F	2.1349	uncontrolled, exhausting to stack
NG boiler	2006	C230-F	1.68	uncontrolled, exhausting to stack
NG boiler	2006	C231-F	1.68	uncontrolled, exhausting to stack
NG boiler	2006	C233-F	0.85	uncontrolled, exhausting to stack
NG boiler	2018	EUN1-HHW-B001	4.00	uncontrolled, exhausting to stack
NG boiler	2018	EUN1-HHW-B002	4.00	uncontrolled, exhausting to stack
NG boiler	2018	EUN1-HHW-B003	4.00	uncontrolled, exhausting to stack
Total			20.48	

(f) Vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids.

(g) Application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings.

(h) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment.

(i) Closed loop heating and cooling systems;

(j) Exposure chambers (“towers”, “columns”), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge.

(k) Replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment.

(l) Heat exchanger cleaning and repair.

(m) Package and Prep operations, exhausting through one (1) stack, identified as S07.

(n) Heat forming, taping, masking, and printing operations exhausting through various building exhausts.

(o) ABRM Catheter Impregnation Process consisting of the following:

(1) A total of two (2) hoods with six (6) emersion tanks per hood and two (2) wells per tank for a total of 24 wells, with a total capacity of 2930 cubic inches and an average weekly usage of 27.5 liters of solvent and antibiotic solution.

(2) A total of three (3) drying hoods for silicon or polyurethane tubes.

(3) A total of one (1) formulation and mixing booth, where the immersion solution is mixed, with potential single HAP (Methanol) emissions of 0.75 tons per year and potential VOC emission of 4.04 tons per year.

(4) A total of one (1) formulation and mixing booth for butyl acetate addition and mixing with a potential VOC emission of 0.67 tons per year.

(p) Paclitaxel Treatment Process consisting of the following:

(1) One (1) raw materials mix hood;

(2) Two (2) Paclitaxel treatment booths; and

(3) Four (4) Paclitaxel aeration booths.

with potential VOC emissions of less than 15 pounds per day for each booth.

A.4 FESOP Applicability [326 IAC 2-8-2]

This stationary source, otherwise required to have a Part 70 permit as described in 326 IAC 2-7-2(a), has applied to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) to renew a Federally Enforceable State Operating Permit (FESOP).

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-8-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-8-4(2)][326 IAC 2-1.1-9.5][IC 13-15-3-6(a)]

(a) This permit, F 105-40744-00030, is issued for a fixed term of ten (10) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date of this permit.

(b) If IDEM, OAQ, upon receiving a timely and complete renewal permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, until the renewal permit has been issued or denied.

B.3 Term of Conditions [326 IAC 2-1.1-9.5]

Notwithstanding the permit term of a permit to construct, a permit to operate, or a permit modification, any condition established in a permit issued pursuant to a permitting program approved in the state implementation plan shall remain in effect until:

(a) the condition is modified in a subsequent permit action pursuant to Title I of the Clean Air Act; or

(b) the emission unit to which the condition pertains permanently ceases operation.

B.4 Enforceability [326 IAC 2-8-6][IC 13-17-12]

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.5 Severability [326 IAC 2-8-4(4)]

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege [326 IAC 2-8-4(5)(D)]

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Provide Information [326 IAC 2-8-4(5)(E)]

(a) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. Upon request, the Permittee shall also furnish to IDEM, OAQ copies of records required to be kept by this permit.

(b) For information furnished by the Permittee to IDEM, OAQ, the Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Certification [326 IAC 2-8-3(d)][326 IAC 2-8-4(3)(C)(i)][326 IAC 2-8-5(1)]

(a) A certification required by this permit meets the requirements of 326 IAC 2-8-5(a)(1) if:

(1) it contains a certification by an "authorized individual", as defined by 326 IAC 2-1.1-1(1), and

(2) the certification states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) The Permittee may use the attached Certification Form, or its equivalent with each submittal requiring certification. One (1) certification may cover multiple forms in one (1) submittal.

(c) An "authorized individual" is defined at 326 IAC 2-1.1-1(1).

B.9 Annual Compliance Certification [326 IAC 2-8-5(a)(1)]

(a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. All certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(c) The annual compliance certification report shall include the following:

(1) The appropriate identification of each term or condition of this permit that is the basis of the certification;

(2) The compliance status;

(3) Whether compliance was continuous or intermittent;

(4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-8-4(3); and

(5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ may require to determine the compliance status of the source.

The submittal by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

B.10 Compliance Order Issuance [326 IAC 2-8-5(b)]

IDEM, OAQ may issue a compliance order to this Permittee upon discovery that this permit is in nonconformance with an applicable requirement. The order may require immediate compliance or contain a schedule for expeditious compliance with the applicable requirement.

B.11 Preventive Maintenance Plan [326 IAC 1-6-3][326 IAC 2-8-4(9)]

(a) A Preventive Maintenance Plan meets the requirements of 326 IAC 1-6-3 if it includes, at a minimum:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

The Permittee shall implement the PMPs.

(b) If required by specific condition(s) in Section D of this permit where no PMP was previously required, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) no later than ninety (90) days after issuance of this permit or ninety (90) days after initial start-up, whichever is later, including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The PMP extension notification does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

The Permittee shall implement the PMPs.

(c) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions. The PMPs and their submittal do not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.12 Emergency Provisions [326 IAC 2-8-12]

(a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation except as provided in 326 IAC 2-8-12.

(b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a health-based or technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:

(1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;

(2) The permitted facility was at the time being properly operated;

(3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;

(4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ or Southeast Regional Office within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality, Compliance and Enforcement Branch), or
Telephone Number: 317-233-0178 (ask for Office of Air Quality, Compliance and Enforcement Branch)
Facsimile Number: 317-233-6865
Southeast Regional Office phone: (812) 358-2027; fax: (812) 358-2058.

(5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-8-4(3)(C)(ii) and must contain the following:

(A) A description of the emergency;

(B) Any steps taken to mitigate the emissions; and

(C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(6) The Permittee immediately took all reasonable steps to correct the emergency.

(c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.

(d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.

(e) The Permittee seeking to establish the occurrence of an emergency shall make records available upon request to ensure that failure to implement a PMP did not cause or contribute to an exceedance of any limitations on emissions. However, IDEM, OAQ may require that the Preventive Maintenance Plans required under 326 IAC 2-8-3(c)(6) be revised in response to an emergency.

(f) Failure to notify IDEM, OAQ by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-8 and any other applicable rules.

(g) Operations may continue during an emergency only if the following conditions are met:

(1) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

(2) If an emergency situation causes a deviation from a health-based limit, the Permittee may not continue to operate the affected emissions facilities unless:

(A) The Permittee immediately takes all reasonable steps to correct the emergency situation and to minimize emissions; and

(B) Continued operation of the facilities is necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw material of substantial economic value.

Any operations shall continue no longer than the minimum time required to prevent the situations identified in (g)(2)(B) of this condition.

B.13 Prior Permits Superseded [326 IAC 2-1.1-9.5]

(a) All terms and conditions of permits established prior to F 105-40744-00030 and issued pursuant to permitting programs approved into the state implementation plan have been either:

(1) incorporated as originally stated,

(2) revised, or

(3) deleted.

(b) All previous registrations and permits are superseded by this permit.

B.14 Termination of Right to Operate [326 IAC 2-8-9][326 IAC 2-8-3(h)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-8-3(h) and 326 IAC 2-8-9.

B.15 Permit Modification, Reopening, Revocation and Reissuance, or Termination [326 IAC 2-8-4(5)(C)][326 IAC 2-8-7(a)][326 IAC 2-8-8]

(a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Federally Enforceable State Operating Permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-8-4(5)(C)]. The notification by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ determines any of the following:

(1) That this permit contains a material mistake.

(2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.

(3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-8-8(a)]

(c) Proceedings by IDEM, OAQ to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-8-8(b)]

(d) The reopening and revision of this permit, under 326 IAC 2-8-8(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ may provide a shorter time period in the case of an emergency. [326 IAC 2-8-8(c)]

B.16 Permit Renewal [326 IAC 2-8-3(h)]

(a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ and shall include the information specified in 326 IAC 2-8-3. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(42). The renewal application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) A timely renewal application is one that is:

(1) Submitted at least nine (9) months prior to the date of the expiration of this permit; and

(2) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(c) If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-8 until IDEM, OAQ takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified, pursuant to 326 IAC 2-8-3(g), in writing by IDEM, OAQ any additional information identified as being needed to process the application.

B.17 Permit Amendment or Revision [326 IAC 2-8-10][326 IAC 2-8-11.1]

(a) Permit amendments and revisions are governed by the requirements of 326 IAC 2-8-10 or 326 IAC 2-8-11.1 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
Any such application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.18 Operational Flexibility [326 IAC 2-8-15][326 IAC 2-8-11.1]

(a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-8-15(b) and (c) without a prior permit revision, if each of the following conditions is met:

(1) The changes are not modifications under any provision of Title I of the Clean Air Act;

(2) Any approval required by 326 IAC 2-8-11.1 has been obtained;

(3) The changes do not result in emissions which exceed the limitations provided in this permit (whether expressed herein as a rate of emissions or in terms of total emissions);

(4) The Permittee notifies the:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

United States Environmental Protection Agency, Region 5
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and

(5) The Permittee maintains records on-site, on a rolling five (5) year basis, which document all such changes and emission trades that are subject to 326 IAC 2-8-15(b)(1) and (c). The Permittee shall make such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ in the notices specified in 326 IAC 2-8-15(b)(1) and (c).

(b) Emission Trades [326 IAC 2-8-15(b)]
The Permittee may trade emissions increases and decreases at the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-8-15(b).

(c) Alternative Operating Scenarios [326 IAC 2-8-15(c)]
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-8-4(7). No prior notification of IDEM, OAQ or U.S. EPA is required.

(d) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

B.19 Source Modification Requirement [326 IAC 2-8-11.1]

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2.

B.20 Inspection and Entry [326 IAC 2-8-5(a)(2)][IC 13-14-2-2][IC 13-17-3-2][IC 13-30-3-1]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a FESOP source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

(c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;

(d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.21 Transfer of Ownership or Operational Control [326 IAC 2-8-10]

(a) The Permittee must comply with the requirements of 326 IAC 2-8-10 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

(b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.22 Annual Fee Payment [326 IAC 2-7-19][326 IAC 2-8-4(6)][326 IAC 2-8-16][326 IAC 2-1.1-7]

(a) The Permittee shall pay annual fees to IDEM, OAQ no later than thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ the applicable fee is due April 1 of each year.

(b) Failure to pay may result in administrative enforcement action or revocation of this permit.

(c) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.23 Credible Evidence [326 IAC 2-8-4(3)][326 IAC 2-8-5][62 FR 8314][326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to

whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

Emission Limitations and Standards [326 IAC 2-8-4(1)]

C.1 Particulate Emission Limitations for Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Overall Source Limit [326 IAC 2-8]

The purpose of this permit is to limit this source's potential to emit to less than major source levels for the purpose of Section 502(a) of the Clean Air Act.

(a) Pursuant to 326 IAC 2-8:

(1) The potential to emit any regulated pollutant, except particulate matter (PM), from the entire source shall be limited to less than one hundred (100) tons per twelve (12) consecutive month period.

(2) The potential to emit any individual hazardous air pollutant (HAP) from the entire source shall be limited to less than ten (10) tons per twelve (12) consecutive month period; and

(3) The potential to emit any combination of HAPs from the entire source shall be limited to less than twenty-five (25) tons per twelve (12) consecutive month period.

(b) Pursuant to 326 IAC 2-2 (PSD), potential to emit particulate matter (PM) from the entire source shall be limited to less than two hundred fifty (250) tons per twelve (12) consecutive month period.

(c) This condition shall include all emission points at this source including those that are insignificant as defined in 326 IAC 2-7-1(21). The source shall be allowed to add insignificant activities not already listed in this permit, provided that the source's potential to emit does not exceed the above specified limits.

(d) Section D of this permit contains independently enforceable provisions to satisfy this requirement.

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-1 (Applicability) and 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A,

Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.4 Open Burning [326 IAC 4-1][IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1.

C.5 Incineration [326 IAC 4-2][326 IAC 9-1-2]

The Permittee shall not operate an incinerator except as provided in 326 IAC 4-2 or in this permit. The Permittee shall not operate a refuse incinerator or refuse burning equipment except as provided in 326 IAC 9-1-2 or in this permit.

C.6 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions).

C.7 Stack Height [326 IAC 1-7]

The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted.

C.8 Asbestos Abatement Projects [326 IAC 14-10][326 IAC 18][40 CFR 61, Subpart M]

(a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.

(b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:

(1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or

(2) If there is a change in the following:

(A) Asbestos removal or demolition start date;

(B) Removal or demolition contractor; or

(C) Waste disposal site.

(c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).

(d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(e) Procedures for Asbestos Emission Control
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-1, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.

(f) Demolition and Renovation
The Permittee shall thoroughly inspect the affected facility or part of the facility where the demolition or renovation will occur for the presence of asbestos pursuant to 40 CFR 61.145(a).

(g) Indiana Licensed Asbestos Inspector
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Licensed Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos.

Testing Requirements [326 IAC 2-8-4(3)]

C.9 Performance Testing [326 IAC 3-6]

(a) For performance testing required by this permit, a test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ if the Permittee submits to IDEM, OAQ a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.10 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements by issuing an order under 326 IAC 2-1.1-11. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-8-4(1)][326 IAC 2-8-5(a)(1)]

C.11 Compliance Monitoring [326 IAC 2-8-4(3)][326 IAC 2-8-5(a)(1)]

(a) For new units:
Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units shall be implemented on and after the date of initial start-up.

(b) For existing units:
Unless otherwise specified in this permit, for all monitoring requirements not already legally required, the Permittee shall be allowed up to ninety (90) days from the date of permit issuance to begin such monitoring. If, due to circumstances beyond the Permittee's control, any monitoring equipment required by this permit cannot be installed and operated no later than ninety (90) days after permit issuance, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

C.12 Instrument Specifications [326 IAC 2-1.1-11][326 IAC 2-8-4(3)][326 IAC 2-8-5(1)]

(a) When required by any condition of this permit, an analog instrument used to measure a parameter related to the operation of an air pollution control device shall have a scale such that the expected maximum reading for the normal range shall be no less than twenty percent (20%) of full scale. The analog instrument shall be capable of measuring values outside of the normal range.

(b) The Permittee may request that the IDEM, OAQ approve the use of an instrument that does not meet the above specifications provided the Permittee can demonstrate that an alternative instrument specification will adequately ensure compliance with permit conditions requiring the measurement of the parameters.

Corrective Actions and Response Steps [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

C.13 Risk Management Plan [326 IAC 2-8-4][40 CFR 68]

If a regulated substance, as defined in 40 CFR 68, is present at a source in more than a threshold quantity, the Permittee must comply with the applicable requirements of 40 CFR 68.

C.14 Response to Excursions or Exceedances [326 IAC 2-8-4][326 IAC 2-8-5]

Upon detecting an excursion where a response step is required by the D Section or an exceedance of a limitation in this permit:

(a) The Permittee shall take reasonable response steps to restore operation of the emissions unit (including any control device and associated capture system) to its normal or usual manner of operation as expeditiously as practicable in accordance with good air pollution control practices for minimizing excess emissions.

(b) The response shall include minimizing the period of any startup, shutdown or malfunction. The response may include, but is not limited to, the following:

(1) initial inspection and evaluation;

(2) recording that operations returned or are returning to normal without operator action (such as through response by a computerized distribution control system); or

(3) any necessary follow-up actions to return operation to normal or usual manner of operation.

(c) A determination of whether the Permittee has used acceptable procedures in response to an excursion or exceedance will be based on information available, which may include, but is not limited to, the following:

(1) monitoring results;

(2) review of operation and maintenance procedures and records; and/or

(3) inspection of the control device, associated capture system, and the process.

(d) Failure to take reasonable response steps shall be considered a deviation from the permit.

(e) The Permittee shall record the reasonable response steps taken.

C.15 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-8-4][326 IAC 2-8-5]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall submit a description of its response actions to IDEM, OAQ no later than seventy-five (75) days after the date of the test.

(b) A retest to demonstrate compliance shall be performed no later than one hundred eighty (180) days after the date of the test. Should the Permittee demonstrate to IDEM, OAQ that retesting in one hundred eighty (180) days is not practicable, IDEM, OAQ may extend the retesting deadline.

(c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The response action documents submitted pursuant to this condition do require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)]

C.16 General Record Keeping Requirements [326 IAC 2-8-4(3)][326 IAC 2-8-5]

(a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. Support information includes the following, where applicable:

(AA) All calibration and maintenance records.
(BB) All original strip chart recordings for continuous monitoring instrumentation.
(CC) Copies of all reports required by the FESOP.

Records of required monitoring information include the following, where applicable:

(AA) The date, place, as defined in this permit, and time of sampling or measurements.
(BB) The dates analyses were performed.
(CC) The company or entity that performed the analyses.
(DD) The analytical techniques or methods used.
(EE) The results of such analyses.
(FF) The operating conditions as existing at the time of sampling or measurement.

These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, for all record keeping requirements not already legally required, the Permittee shall be allowed up to ninety (90) days from the date of permit issuance or the date of initial start-up, whichever is later, to begin such record keeping.

C.17 General Reporting Requirements [326 IAC 2-8-4(3)(C)][326 IAC 2-1.1-11]

(a) The Permittee shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Proper notice submittal under Section B -Emergency Provisions satisfies the reporting requirements of this paragraph. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported except that a deviation required to be reported pursuant to an applicable requirement that exists independent of this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. This report shall be submitted not later than thirty (30) days after the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1). A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

(b) The address for report submittal is:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(d) Reporting periods are based on calendar years, unless otherwise specified in this permit. For the purpose of this permit "calendar year" means the twelve (12) month period from January 1 to December 31 inclusive.

Stratospheric Ozone Protection

C.18 Compliance with 40 CFR 82 and 326 IAC 22-1

Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with applicable standards for recycling and emissions reduction.

SECTION D.1 EMISSIONS UNIT OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, where:

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non-regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) During aeration cycle, zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01.

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.1.1 Volatile Organic Compounds (VOC) BACT [326 IAC 8-1-6]

Pursuant to FESOP F105-8436-00030, issued on February 16, 1998, and in order to render the requirements of 326 IAC 8-1-6 (VOC Rules: General Reduction Requirements for New Facilities), the following control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operations S1 through S7. The control technology used to comply with the requirements of 40 CFR 63.360 through 63.367, which apply to the sterilization process, in addition to the following:

(a) A single nonregenerable dry bed reactor to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, to control the seven (7) sterilization chamber exhaust vents, identified as units S1 through S7.

(b) A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent

whichever is less stringent, to control emissions from the fourteen (14) aeration rooms.

Compliance with the above limit in this condition shall satisfy the requirements of 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Note: The source will not be required to operate the dry bed reactor to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9, approved for construction in 2012. Although S8 and S9 are not subject to the requirements of 326 IAC 8-1-6, the Permittee voluntarily installed three (3) dry bed reactors (in parallel) to reduce emissions from the back vents from sterilizers S8 and S9.

Note: The Permittee voluntarily installed fifteen (15) dry bed reactors to minimize, to the extent feasible, contributions from fugitive sources of ethylene oxide. Accordingly, the source will not be required to control the facility room vents from SRV1 through SRV7, the ethylene oxide dispensing room or the control equipment for secondary abatement of the primary wet scrubber.

D.1.2 Hazardous Air Pollutants (HAPs) Minor Limits [326 IAC 2-8-4]

Pursuant to 326 IAC 2-8, the total ethylene oxide emissions from the nine (9) ethylene oxide sterilization chambers and the fourteen (14) aeration rooms shall be less than 9.42 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month

Compliance with the above limit, combined with the potential to emit ethylene oxide from other emission units at the source, shall limit the ethylene oxide from the entire source to less than 10 tons per year, total HAPs to less than twenty-five (25) tons per year and render the requirements of 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP) not applicable.

D.1.3 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan is required for this facility and any control devices. Section B - Preventive Maintenance Plan contains the Permittee's obligation with regard to the preventive maintenance plan required by this condition.

Compliance Determination Requirements [326 IAC 2-8-4(1)]

D.1.4 VOC and HAPs [326 IAC 8-1-6][326 IAC 2-8-4]

(a) In order to assure compliance with Conditions D.1.1, and D.1.2, the primary wet acid scrubber and the single non-regenerable dry bed reactor shall be in operation and control emissions from the seven (7) ethylene oxide sterilization chambers S1 through S7 at all times the ethylene oxide sterilization chambers are in operation.

(b) In order to assure compliance with Conditions D.1.1, and D.1.2, the primary wet acid scrubber shall be in operation and control emissions from the two (2) ethylene oxide sterilization chambers S8 and S9 at all times the ethylene oxide sterilization chambers are in operation.

(c) In order to assure compliance with Conditions D.1.1, and D.1.2, the three (3) dry bed reactors with or without the wet acid pre-scrubber shall be in operation and control emissions from the fourteen (14) aeration rooms at all times the fourteen (14) aeration rooms are in operation.

D.1.5 Testing Requirements [326 IAC 2-1.1-11][40 CFR Part 63, Subpart O]

(a) Not later than 180 days after the issuance of F105-40744-00030, the Permittee shall perform test on each of the following control devices, in order to demonstrate compliance with Condition D.1.1, Condition D.1.2, and Condition E.1.2:

(1) The one (1) primary wet acid scrubber, exhausting to stack PS01, controlling ethylene oxide emissions from the two (2) sterilization chamber S8 through S9;

(2) The single non-regenerable dry bed reactor , exhausting to stack SV01, controlling ethylene oxide Chamber Exhaust Vent (CEV) emissions from the seven (7) sterilization chambers S1 through S7;

(3) The one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), exhausting to stack HV01, controlling ethylene oxide emissions from the fourteen (14) aeration rooms;

utilizing the procedures listed in 40 CFR 63.7 of Subpart A, the procedures listed in 40 CFR 63.363, the test methods listed in 40 CFR 63.365. During the performance test, the owner or operator shall determine the efficiency of the control devices and the site-specific operating parameters for each of the wet acid scrubbers. This test shall be repeated at least once every five (5) years from the date of the most recent valid compliance demonstration. Testing shall be conducted in accordance with the provisions of 326 IAC 3-6 (Source Sampling Procedures).

(b) Section C - Performance Testing contains the Permittee's obligation with regard to the performance testing required by this condition.

Compliance Monitoring Requirements [326 IAC 2-8-4(1)][326 IAC 2-8-5(a)(1)]

D.1.6 Monitoring

To demonstrate the compliance status with the control efficiency and emission limitations requirements in conditions D.1.1, and D.1.2:

(a) For the Single Non-Regenerable Dry Bed Reactor and Three (3) Dry Bed Reactors; the Permittee shall comply with the following:

(1) Monitor and record the number of equivalent sterilization cycles performed while the bed is in service for each of the dry bed reactors; single non-regenerable dry bed reactor controlling ethylene oxide emissions from the seven (7) sterilization chamber exhaust vents (back vents) for units S1 through S7 and the three (3) dry bed reactors controlling ethylene oxide emissions from the fourteen (14) aerations rooms, identified as HC1 through HC14.

(2) Keep a record of the number of sterilization cycles run for sterilizer units S1 through S7, convert this to equivalent cycles for a 512 ft^3 sterilizer, and keep a daily running record of total equivalent cycles. The equivalent sterilization cycles shall not exceed 2,917. Each of the dry bed reactor's bed material shall be removed and replaced with fresh reactant once this maximum sterilization cycles is reached.

(3) The gas chromatography shall be calibrated, maintained and operated for measuring the outlet concentration from the single dry bed reactor associated with sterilization chambers (S1-S7) and dry bed reactors associated with the fourteen (14) aerations rooms, identified as HC1 through HC14, once per week. In the event the on-site gas chromatograph malfunctions, arrangements will be made for interim weekly off-site analysis via gas chromatography. This does not relieve the Permittee of the responsibility to properly maintain the on-site gas chromatograph.

(b) For the Primary Wet Acid Scrubber and Wet Acid Pre-Scrubber:

The Permittee shall measure and record once per week the level of the scrubber liquor in the single recirculation tank serving both the primary wet acid scrubber controlling sterilization chamber vents and the wet acid pre-scrubber controlling aeration room vents per 40 CFR 63.364(b)(2). The Permittee shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e. a marker on the tank wall, a dipstick, a magnetic indicator, etc.) to ensure the scrubber liquor level remains below the maximum allowable height of 84.75 inches above floor elevation.

When for any one reading the scrubber liquor level range is above the above mentioned maximum height of 84.75 inches, the Permittee shall take a reasonable response. Section C - Response to Excursions or Exceedances contains the Permittee's obligation with regard to the response steps required by this condition. A reading that is above the above mentioned maximum liquor level is not a deviation from this permit. Failure to take response steps shall be considered a deviation from this permit.

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)]

D.1.7 Record Keeping Requirements

(a) To document the compliance status with Conditions D.1.1, D.1.2, and D.1.6, the Permittee shall maintain records in accordance with (1) and (6) below. Records of all data and operating parameters shall be complete and sufficient to establish compliance with the limits established in Condition D.1.1, D.1.2, and D.1.6 based on

(1) The number of equivalent sterilization cycles performed daily while the single non-regenerable dry bed reactor controlling chamber exhaust vents is in service; and

(2) The number of equivalent sterilization cycles performed daily while the three (3) dry bed reactors controlling aeration room exhaust are in service.

(3) Permittee shall maintain records of the weekly Ethylene Oxide concentration readings from the dry bed outlets associated with Exhaust SV01.

(4) All corrective and preventive maintenance actions taken in association with the ethylene oxide emissions control equipment.

(5) All maintenance logs, calibration checks, and other required maintenance activities associated with the ethylene oxide emissions control equipment.

(6) The Permittee shall maintain a record of any gas chromatograph downtime associated with the ethylene oxide concentration monitoring system including the following information:

(A) Date of monitoring system downtime.
(B) Time of commencement and completion of each downtime.
(C) Reason for each downtime.
(D) Nature of system repairs and adjustments.

(b) To document the compliance status with Condition D.1.6 (b) shall measure and record once per week the level of the scrubber liquor in the recirculation tank. The Permittee shall include in its weekly record when the readings are not taken and the reason for the lack of the readings (e.g., the process did not operate that day).

(c) Section C - General Record Keeping Requirements contains the Permittee's obligation with regard to the records required by this condition.

D.1.8 Reporting Requirements

A quarterly summary of the information to document the compliance status with Condition D.1.2 shall be submitted using the reporting forms located at the end of this permit, or their equivalent, within no later than thirty (30) days after the end of the quarter being reported. Section C - General Reporting contains the Permittee's obligation with regard to the reporting required by this condition. The report submitted by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an “authorized individual” as defined by 326 IAC 2-1.1-1(1).

SECTION D.2 EMISSIONS UNIT OPERATION CONDITIONS

Emissions Unit Description:

(h) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.2.1 Particulate Emission Limitations for manufacturing Processes [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), (Particulate Emission Limitations for manufacturing Processes), the particulate emissions from the brazing equipment, cutting torches, soldering equipment and welding equipment shall not exceed 0.551 pound per hour.

D.2.2 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan is required for these facilities. Section B - Preventive Maintenance Plan contains the Permittee's obligation with regard to the preventive maintenance plan required by this condition.

SECTION D.3 EMISSIONS UNIT OPERATION CONDITIONS

Emissions Unit Description: Insignificant Activities

(e) Natural gas-fired combustion sources including the following:

Emission units	Construction	ID	Heat Input Capacity (MMBtu/hr)	
NG boiler	2003	C241-F	2.1349	uncontrolled, exhausting to stack
NG boiler	2003	C242-F	2.1349	uncontrolled, exhausting to stack
NG boiler	2006	C230-F	1.68	uncontrolled, exhausting to stack
NG boiler	2006	C231-F	1.68	uncontrolled, exhausting to stack
NG boiler	2006	C233-F	0.85	uncontrolled, exhausting to stack
NG boiler	2018	EUN1-HHW-B001	4.00	uncontrolled, exhausting to stack
NG boiler	2018	EUN1-HHW-B002	4.00	uncontrolled, exhausting to stack
NG boiler	2018	EUN1-HHW-B003	4.00	uncontrolled, exhausting to stack
Total			20.48	

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.3.1 Particulate Emission Limitations for Sources of Indirect Heating [326 IAC 6-2-4]

Pursuant to 326 IAC 6-2-4, particulate emissions from each individual boiler shall be limited as follows:

Unit ID	PM Emission Limit (lb/MMBtu)
C241-F	0.60
C242-F	0.60
C230-F	0.50
C231-F	0.50
C233-F	0.50
EUN1-HHW-B001	0.44
EUN1-HHW-B002	0.44
EUN1-HHW-B003	0.44

D.3.1 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan is required for these facilities. Section B - Preventive Maintenance Plan contains the Permittee's obligation with regard to the preventive maintenance plan required by this condition.

SECTION E.1 NESHAP

Emissions Unit Description:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, where:

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non-regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) During aeration cycle, zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01.

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements

E.1.1 General Provisions Relating to NESHAP O [326 IAC 20-1][40 CFR Part 63, Subpart A]

(a) The requirements of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facilities described in this section except as otherwise specified in 40 CFR 63, Subpart O.

(b) Pursuant to 40 CFR 63.10, the Permittee shall submit all required notifications and reports to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

E.1.2 Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP [40 CFR Part 63, Subpart O][326 IAC 20-5]

The Permittee shall comply with the following provisions of 40 CFR Part 63, Subpart O (included as Attachment A to the operating permit), which are incorporated by reference as 326 IAC 20-5, for the emission unit(s) listed above: as follows:

(1) 40 CFR 63.360,
(2) 40 CFR 63.361,
(3) 40 CFR 63.362,
(4) 40 CFR 63.363(a), (b)(1), (b)(2), (c), (e), (f),
(5) 40 CFR 63.364(a), (b), (d), (e),
(6) 40 CFR 63.365,
(7) 40 CFR 63.366,
(8) 40 CFR 63.367,
(9) 40 CFR 63.368.

SECTION E.2 NESHAP

Facility Description [326 IAC 2-8-4(10)]:

(e) One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and constructed in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

[The diesel-fired emergency generator, identified as Unit #1 is an existing affected facility under 40 CFR 63, Subpart ZZZZ.]

(f) One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and constructed in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

[The diesel-fired emergency generator, identified as Unit #2 is an existing affected facility under 40 CFR 63, Subpart ZZZZ.]

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements

E.2.1 General Provisions Relating to NESHAP ZZZZ [326 IAC 20-1][40 CFR Part 63, Subpart A]

(a) Pursuant to 40 CFR 63.1 the Permittee shall comply with the provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated by reference as 326 IAC 20-1, for the emission units listed above, except as otherwise specified in 40 CFR Part 63, Subpart ZZZZ.

(b) Pursuant to 40 CFR 63.10, the Permittee shall submit all required notifications and reports to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

E.2.2 National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines [326 IAC 20-82][40 CFR 63, Subpart ZZZZ]

The Permittee shall comply with the following provisions of 40 CFR Part 63, Subpart ZZZZ (included as Attachment B to the operating permit), which are incorporated by reference as 326 IAC 20-82, for the emission unit(s) listed above:

(1) 40 CFR 63.6580
(2) 40 CFR 63.6585
(3) 40 CFR 63.6590(a)(1)(iii)
(4) 40 CFR 63.6640(f)(1), (2)(i), (3), (4)

E.2.3 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan is required for these facilities and any control devices. Section B - Preventive Maintenance Plan contains the Permittee's obligation with regard to the preventive maintenance plan required by this condition.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP) CERTIFICATION

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F 105-40744-00030

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

☐ Annual Compliance Certification Letter

☐ Test Result (specify)_____

☐ Report (specify)_____

☐ Notification (specify)_____

☐ Affidavit (specify)_____

☐ Other (specify)_____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Date:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
Phone: (317) 233-0178
Fax: (317) 233-6865

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
EMERGENCY OCCURRENCE REPORT

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F 105-40744-00030

This form consists of 2 pages **Page 1 of 2**

□ This is an emergency as defined in 326 IAC 2-7-1(12)
- The Permittee must notify the Office of Air Quality (OAQ), within four (**4**) daytime business hours (1-800-451-6027 or 317-233-0178, ask for Compliance Section); and
- The Permittee must submit notice in writing or by facsimile within two (**2**) working days (Facsimile Number: 317-233-6865), and follow the other requirements of 326 IAC 2-8-12

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A **Page 2 of 2**

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO_2, VOC, NO_X, CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by:_____

Title / Position:_____

Date:_____

Phone: _____

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH

FESOP Quarterly Report

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F 105-40744-00030
Facility: Nine (9) ethylene oxide sterilization chambers and the fourteen (14) aeration rooms
Parameter: HAP Emission
Limit: Shall not exceed 9.42 tons per twelve (12) consecutive month period, with compliance determined at the end of each month

QUARTER : _____YEAR:_____

Month	Column 1	Column 2	Column 1 + Column 2
	This Month (tons/yr)	Previous 11 Months (tons/yr)	12 Month Total (tons/yr)

☐ No deviation occurred in this quarter.

☐ Deviation/s occurred in this quarter.
Deviation has been reported on:_____

Submitted by: _____
Title / Position: _____
Signature: _____
Date: _____
Phone: _____

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH
FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F 105-40744-00030

Months: _____ to _____ Year: _____

Page 1 of 2

This report shall be submitted quarterly based on a calendar year. Proper notice submittal under Section B -Emergency Provisions satisfies the reporting requirements of paragraph (a) of Section C-General Reporting. Any deviation from the requirements of this permit, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. A deviation required to be reported pursuant to an applicable requirement that exists independent of the permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".

□ NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.

□ THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Form Completed by:_____

Title / Position:_____

Date:_____

Phone: _____

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for an Administrative Amendment to a Federally Enforceable State Operating Permit (FESOP) Renewal

Source Description and Location

Source Name:	**Cook Incorporated**
Source Location:	**6330 North Matthews Drive, Ellettsville, IN 47429**
County:	**Monroe**
SIC Code:	**3841 (Surgical and Medical Instruments and Apparatus)**
Operation Permit No.:	**F 105-40744-00030**
Operation Permit Issuance Date:	**August 30, 2019**
Administrative Amendment No.:	**105-42357-00030**
Permit Reviewer:	**Jared Karban**

Existing Approvals

The source was issued FESOP Renewal No. 105-40744-00030 on August 30, 2019. There have been no subsequent approvals issued.

County Attainment Status

The source is located in Monroe County.

Pollutant	Designation
SO_2	Better than national standards.
CO	Unclassifiable or attainment effective November 15, 1990.
O_3	Unclassifiable or attainment effective January 16, 2018, for the 2015 8-hour ozone standard.
$PM_{2.5}$	Unclassifiable or attainment effective April 15, 2015, for the 2012 annual $PM_{2.5}$ standard.
$PM_{2.5}$	Unclassifiable or attainment effective December 13, 2009, for the 2006 24-hour $PM_{2.5}$ standard.
PM_{10}	Unclassifiable effective November 15, 1990.
NO_2	Unclassifiable or attainment effective January 29, 2012, for the 2010 NO_2 standard.
Pb	Unclassifiable or attainment effective December 31, 2011, for the 2008 lead standard.

(a) Ozone Standards
Volatile organic compounds (VOC) and Nitrogen Oxides (NO_x) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NO_x emissions are considered when evaluating the rule applicability relating to ozone. Monroe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NO_x emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(b) $PM_{2.5}$
Monroe County has been classified as attainment for $PM_{2.5}$. Therefore, direct $PM_{2.5}$, SO_2, and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(c) Other Criteria Pollutants
Monroe County has been classified as attainment or unclassifiable in Indiana for all the other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

Fugitive Emissions

Since this type of operation is not one (1) of the twenty-eight (28) listed source categories under 326 IAC 2-2-1(ff)(1), 326 IAC 2-3-2(g), or 326 IAC 2-7-1(22)(B), and there is no applicable New Source Performance Standard or National Emission Standard for Hazardous Air Pollutants that was in effect on August 7, 1980, fugitive emissions are not counted toward the determination of PSD, Emission Offset, and Part 70 Permit applicability.

The fugitive emissions of hazardous air pollutants (HAP) are counted toward the determination of Part 70 Permit applicability and source status under Section 112 of the Clean Air Act (CAA).

Greenhouse Gas (GHG) Emissions

On June 23, 2014, in the case of *Utility Air Regulatory Group v. EPA*, cause no. 12-1146, (available at http://www.supremecourt.gov/opinions/13pdf/12-1146_4g18.pdf) the United States Supreme Court ruled that the U.S. EPA does not have the authority to treat greenhouse gases (GHGs) as an air pollutant for the purpose of determining operating permit applicability or PSD Major source status. On July 24, 2014, the U.S. EPA issued a memorandum to the Regional Administrators outlining next steps in permitting decisions in light of the Supreme Court's decision. U.S. EPA's guidance states that U.S. EPA will no longer require PSD or Title V permits for sources "previously classified as 'Major' based solely on greenhouse gas emissions."

The Indiana Environmental Rules Board adopted the GHG regulations required by U.S. EPA at 326 IAC 2-2-1(zz), pursuant to Ind. Code § 13-14-9-8(h) (Section 8 rulemaking). A rule, or part of a rule, adopted under Section 8 is automatically invalidated when the corresponding federal rule, or part of the rule, is invalidated. Due to the United States Supreme Court Ruling, IDEM, OAQ cannot consider GHG emissions to determine operating permit applicability or PSD applicability to a source or modification.

Source Status - Existing Source

The table below summarizes the potential to emit of the entire source, prior to the administrative amendment, after consideration of all enforceable limits established in the effective permits. If the control equipment has been determined to be integral, the table reflects the potential to emit (PTE) after consideration of the integral control device.

	Source-Wide Emissions Prior to Administrative Amendment (ton/year)								
	PM[1]	**PM_{10}[1]**	**$PM_{2.5}$[1, 2]**	**SO_2**	**NO_X**	**VOC**	**CO**	**Single HAP[3]**	**Total HAPs**
Total PTE of Entire Source Excluding Fugitive Emissions*	1.14	1.29	1.29	4.88	37.43	31.38	13.95	9.42 (Ethylene Oxide)	10.53
Title V Major Source Thresholds	NA	100	100	100	100	100	100	10	25
PSD Major Source Thresholds	250	250	250	250	250	250	250	--	--
Emission Offset Major Source Thresholds	---	NA	NA	NA	NA	NA	NA	--	--

[1]Under the Part 70 Permit program (40 CFR 70), PM_{10} and $PM_{2.5}$, not particulate matter (PM), are each considered as a "regulated air pollutant."

[2]$PM_{2.5}$ listed is direct $PM_{2.5}$.

[3]Single highest source-wide HAP

*Fugitive HAP emissions are always included in the source-wide emissions.

(a) This existing source is not a major stationary source, under PSD (326 IAC 2-2), because no PSD regulated pollutant is emitted at a rate of two hundred fifty (250) tons per year or more and it is not one of the twenty-eight (28) listed source categories, as specified in 326 IAC 2-2-1(ff)(1).

(b) This existing source is not a major source of HAP, as defined in 40 CFR 63.2, because HAP emissions are less than ten (10) tons per year for any single HAP and less than twenty-five (25) tons per year of a combination of HAPs.

(c) These emissions are based on the TSD of FESOP No. 105-40744-00030, issued on August 30, 2019.

Description of Amendment

The Office of Air Quality (OAQ) has reviewed an application, submitted by Cook Incorporated on December 23, 2019, relating to adding eighteen (18) dry bed reactors through Voluntary Emissions Reduction for VOC and HAPs for internal quality purposes.

The following is a list of the emission units with the new voluntary pollution control devices:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting

through a vacuum pump to one (1) primary wet acid scrubber and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel which exhausts through one (1) stack, identified as RSV01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, where:

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non-regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) ***

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(d) Eight (8) Facility Room Vents, identified as Sterilization Room Vents (SRV) SRV1 through SRV7 and the ethylene oxide dispensing room vents, exhausting through fifteen (15) voluntary non-regenerable dry bed units exhausting through five (5) independent stacks.

(1) SRV1 and SRV2 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RSV01.

(2) SRV3 and SRV4 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV02.

(3) SRV5 and SRV6 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV03.

(4) EO Dispensing Room Vent exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV04.

(5) SRV7 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV05.

Enforcement Issues

There are no pending enforcement actions related to this administrative amendment.

Emission Calculations

See Appendix A of this Technical Support Document for detailed emission calculations.

Permit Level Determination – FESOP Administrative Amendment

Pursuant to 326 IAC 2-1.1-1(12), Potential to Emit is defined as “the maximum capacity of a stationary source or emission unit to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA, IDEM, or the appropriate local air pollution control agency.”

The following table is used to determine the appropriate permit level under 326 IAC 2-8-10 (Administrative Permit Amendments). This table reflects the PTE before controls of the administrative

amendment. If the control equipment has been determined to be integral, the table reflects the potential to emit (PTE) after consideration of the integral control device.

	PTE Increase of the Modified Emission Units/Processes (ton/year)								
Process / Emission Unit	**PM**	**PM_{10}**	**$PM_{2.5}$[1]**	**SO_2**	**NO_X**	**VOC**	**CO**	**Single HAP[2]**	**Total HAPs**
PTE Before Modification (S1-S7)	-	-	-	-	-	37.88	-	37.88	37.88
PTE After Modification (S1-S7)	-	-	-	-	-	37.88	-	37.88	37.88
PTE Increase (S1-S7)	-	-	-	-	-	*0*	-	*0*	*0*
PTE Before Modification (S8-S9)	-	-	-	-	-	24.04	-	24.04	24.04
PTE After Modification (S8-S9)	-	-	-	-	-	24.04	-	24.04	24.04
PTE Increase (S8-S9)	-	-	-	-	-	*0*	-	*0*	*0*
Total PTE Increase of the Modified Emission Unit(s)/Process	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

[1]$PM_{2.5}$ listed is direct $PM_{2.5}$.

[2]Single highest HAP.

Appendix A of this TSD reflects the detailed potential emissions of the administrative amendment.

Pursuant to 326 IAC 2-8-10(a)(2)(B), this change to the permit is considered an administrative amendment because the permit is amended to change descriptive information concerning the source or an emissions unit, where the revision will not trigger a new applicable requirement. The Permittee is adding voluntary emission control equipment.

PTE of the Entire Source After Issuance of the FESOP Administrative Amendment

The table below summarizes the after issuance source-wide potential to emit, reflecting all limits, of the emission units. Any control equipment is considered federally enforceable only after issuance of the administrative amendment, and only to the extent that the effect of the control equipment is made practically enforceable in the permit. If the control equipment has been determined to be integral, the table reflects the potential to emit (PTE) after consideration of the integral control device.

	Source-Wide Emissions After Issuance (ton/year)								
	PM[1]	**PM_{10}[1]**	**$PM_{2.5}$[1, 2]**	**SO_2**	**NO_X**	**VOC**	**CO**	**Single HAP[3]**	**Total HAPs**
Total PTE of Entire Source Excluding Fugitives*	1.14	1.29	1.29	4.88	37.43	31.38	13.95	9.42	10.53
Title V Major Source Thresholds	NA	100	100	100	100	100	100	10	25
PSD Major Source Thresholds	250	250	250	250	250	250	250	--	--
Emission Offset Major Source Thresholds	---	NA	NA	NA	NA	NA	NA	--	--

[1]Under the Part 70 Permit program (40 CFR 70), PM_{10} and $PM_{2.5}$, not particulate matter (PM), are each considered as a "regulated air pollutant."

[2]$PM_{2.5}$ listed is direct $PM_{2.5}$.

[3]Single highest source-wide HAP (Ethylene oxide)

*Fugitive HAP emissions are always included in the source-wide emissions.

Appendix A of this TSD reflects the detailed potential to emit of the entire source after issuance.

(a) This existing Title V minor stationary source will continue to be minor under 326 IAC 2-7 because the potential to emit criteria pollutants and HAPs from the entire source will continue to be less than or limited to less than the Title V major source threshold levels. Therefore, the source is subject to the provisions of 326 IAC 2-8 (FESOP) and is an area source under Section 112 of the Clean Air Act (CAA).

(b) This existing minor PSD stationary source will continue to be minor under 326 IAC 2-2 because the potential to emit of all PSD regulated pollutants from the entire source will continue to be less than the PSD major source thresholds. Therefore, pursuant to 326 IAC 2-2, the PSD requirements do not apply.

Federal Rule Applicability Determination

Due to the administrative amendment, federal rule applicability has been reviewed as follows:

New Source Performance Standards (NSPS):

(a) There are no New Source Performance Standards (40 CFR Part 60) and 326 IAC 12 included for this administrative amendment.

National Emission Standards for Hazardous Air Pollutants (NESHAP):

(a) There are no National Emission Standards for Hazardous Air Pollutants under 40 CFR 63, 326 IAC 14 and 326 IAC 20 included for this administrative amendment.

Compliance Assurance Monitoring (CAM):

Pursuant to 40 CFR 64.2, Compliance Assurance Monitoring (CAM) is not included in the permit, because the unlimited potential to emit of the source is limited to less than the Title V major source thresholds and the source is not required to obtain a Part 70 or Part 71 permit.

State Rule Applicability - Entire Source

Due to this administrative amendment, state rule applicability has not changed for the source since the only change was related to voluntary emissions reductions.

State Rule Applicability – Individual Facilities

Due to the administrative amendment, state rule applicability has not changed for any emission units since the only change was related to voluntary emissions reductions.

Compliance Determination and Monitoring Requirements

There are no new or modified compliance requirements included with this administrative amendment.

Proposed Changes

The following changes listed below are due to the administrative amendment. Deleted language appears as ~~strikethrough~~ text and new language appears as **bold** text:

(1) Added dry bed reactors to the permit in section A.1 at the request of the permittee through voluntary emission reduction and adjusted subsequent lettering:

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-8-3(c)(3)]

This stationary source consists of the following emission units and pollution control devices:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber **and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel** which exhausts through one (1) stack, identified as **RSV01**~~PS01~~, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber **and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel** which exhausts through one (1) stack, identified as **RSV01**~~PS01~~; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, **where:**

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non-regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) During aeration cycle,~~of which~~ zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01.

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(d) Eight (8) Facility Room Vents, identified as Sterilization Room Vents (SRV) SRV1 through SRV7 and the ethylene oxide dispensing room vents, exhausting through fifteen (15) voluntary non-regenerable dry bed units exhausting through five (5) independent stacks.

(1) SRV1 and SRV2 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RSV01.

(2) SRV3 and SRV4 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV02.

(3) SRV5 and SRV6 exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV03.

(4) EO Dispensing Room Vent exhausting through three (3) non-regenerable dry bed reactors (in parallel) and exhausted through one (1) stack identified as RV04.

(5) SRV7 exhausting through three (3) non-regenerable dry bed reactors (in

parallel) and exhausted through one (1) stack identified as RV05.

*****

(2) Changed language in section D.1 in the Facility Description box to match the new emission unit descriptions by adding notes relevant to the Voluntary Reductions and added a note about the addition of the new dry bed reactors to the end of section D.1.1:

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber **and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel** which exhausts through one (1) stack, identified as **RSV01**~~PS01~~, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber **and modified in 2019 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel** which exhausts through one (1) stack, identified as **RSV01**~~PS01~~; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, **where:**

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non- regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) During aeration cycle, ~~of which~~ zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01.

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.1.1 Volatile Organic Compounds (VOC) BACT [326 IAC 8-1-6]

Pursuant to FESOP F105-8436-00030, issued on February 16, 1998, and in order to render the requirements of 326 IAC 8-1-6 (VOC Rules: General Reduction Requirements for New Facilities), the following control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operations S1 through S7. The control technology used to comply with the requirements of 40 CFR 63.360 through 63.367, which apply to the sterilization process, in addition to the following:

(a) A single nonregenerable dry bed reactor to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, to control the seven (7) sterilization chamber exhaust vents, identified as units S1 through S7.

(b) A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent whichever is less stringent, to control emissions from the fourteen (14) aeration rooms.

Compliance with the above limit in this condition shall satisfy the requirements of 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Note: The source will not be required to operate the dry bed reactor to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9, approved for construction in 2012. Although S8 and S9 are not subject to the requirements of 326 IAC 8-1-6, the Permittee voluntarily installed three (3) dry bed reactors (in parallel) to reduce emissions from the back vents from sterilizers S8 and S9.

Note: The Permittee voluntarily installed fifteen (15) dry bed reactors to minimize, to the extent feasible, contributions from fugitive sources of ethylene oxide. Accordingly, the source will not be required to control the facility room vents from SRV1 through SRV7, the ethylene oxide dispensing room or the control equipment for secondary abatement of the primary wet scrubber.

*****

(3) Changed grammatical inconsistencies that said "each" in reference to a single dry bed reactor (making it seem like there could be more than one) and made the word "reactors" plural for the series of three reactors in section D.1.6 so that requirements designated to the certain unit are clearer, at the request of the permittee. In addition, Condition D.1.7 was edited to fix a reference error:

Compliance Monitoring Requirements [326 IAC 2-8-4(1)][326 IAC 2-8-5(a)(1)]

D.1.6 Monitoring

To demonstrate the compliance status with the control efficiency and emission limitations requirements in conditions D.1.1, and D.1.2:

(a) For the Single Non-Regenerable Dry Bed Reactor and Three (3) Dry Bed Reactors; the Permittee shall comply with the following:

*****

(3) The gas chromatography shall be calibrated, maintained and operated for measuring the outlet concentration from ~~each of~~ the **single** dry bed reactor associated with sterilization chambers (S1-S7) and dry bed reactor**s** associated with the fourteen (14) aerations rooms, identified as HC1 through HC14, once **per** ~~a~~ week. In the event the on-site gas chromatograph malfunctions, arrangements will be made for interim weekly off-site analysis via gas chromatography. This does not relieve the Permittee of the responsibility to properly maintain the on-site gas chromatograph.

*****

D.1.7 Record Keeping Requirements

*****

(b) To document the compliance status with Condition D.1.6 (**b**~~d~~) shall measure and record once per week the level of the scrubber liquor in the recirculation tank. The Permittee shall include in its weekly record when the readings are not taken and the reason for the lack of the readings (e.g., the process did not operate that day).

(c) Section C - General Record Keeping Requirements contains the Permittee's obligation with regard to the records required by this condition.

*****

(4) Removed reference to the dry bed reactors from D.1.5 as requested by the source. Based on conversations with the source and internal to IDEM, referencing operating parameters of the dry bed reactors causes confusion between section D.1.5 (Compliance Determination) and D.1.6 (Compliance Monitoring). The operating parameter for each dry bed unit is met through Compliance Monitoring, which is defined in D.1.6 and D.1.7. Therefore, the reference to the dry bed reactors have been removed, as follows:

***

D.1.5 Testing Requirements [326 IAC 2-1.1-11][40 CFR Part 63, Subpart O]

(a) Not later than 180 days after the issuance of F105-40744-00030, the Permittee shall perform test on each of the following control devices, in order to demonstrate compliance with Condition D.1.1, Condition D.1.2, and Condition E.1.2:

***

utilizing the procedures listed in 40 CFR 63.7 of Subpart A, the procedures listed in 40 CFR 63.363, the test methods listed in 40 CFR 63.365. During the performance test, the owner or operator shall determine the efficiency of the control devices and the site-specific operating parameters for each of the wet acid scrubbers ~~and the dry bed reactors~~. This test shall be repeated at least once every five (5) years from the date of the most recent valid compliance demonstration. Testing shall be conducted in accordance with the provisions of 326 IAC 3-6 (Source Sampling Procedures).

(b) Section C - Performance Testing contains the Permittee's obligation with regard to the performance testing required by this condition.

*****

(5) Changed language in section E.1 in the Emissions Unit Description box to match the new emission unit descriptions for said units:

Emissions Unit Description:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber **and modified in 2020 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel** which exhausts through one (1) stack, identified as **RSV01**~~PS01~~, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01.

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, constructed in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber **and modified in 2020 to add three (3) voluntary secondary non-regenerable dry bed reactors in parallel** which exhausts through one (1) stack, identified as **RSV01**~~PS01~~; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, **where:**

(1) During aeration room loading, an aeration bypass exhausts through three (3) voluntary non- regenerable dry bed reactors (in parallel), which exhaust through one (1) stack identified as HV02.

(2) During aeration cycle, ~~of which~~ zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of

which exhaust through one (1) stack, identified as HV01.

[Nine (9) ethylene oxide sterilization chambers (S1-S9) and fourteen (14) aeration rooms, (HC1-HC14 are existing affected facilities under 40 CFR 63, Subpart O.]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Conclusion and Recommendation

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant. An application for the purposes of this review was received on December 23, 2019.

IDEM Contact

(a) If you have any questions regarding this permit, please contact Jared Karban, Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana 46204-2251, or by telephone at (317) 233-4230 or (800) 451-6027, and ask for Jared Karban or (317) 233-4230.

(b) A copy of the findings is available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/

(c) For additional information about air permits and how the public and interested parties can participate, refer to the IDEM Air Permits page on the Internet at: http://www.in.gov/idem/airquality/2356.htm; and the Citizens' Guide to IDEM on the Internet at: http://www.in.gov/idem/6900.htm.

Appendix A: Emissions Calculations
Source-Wide Summary

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

Uncontrolled Potential To Emit of the Entire Source (tons/year)

Process / Emission Unit	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	Total HAPs	Single HAP	
Sterilization (S1 to S7)	-	-	-	-	-	37.88	-	37.88	37.88	Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-	24.04	-	24.04	24.04	
Surface Coating	-	-	-	-	-	2.05	-	0.01	0.01	Methaol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	0.00	0.00	
Catheter Impregnation	-	-	-	-	-	4.04	-	0.75	0.75	Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	0.00	0.00	
Boilers	0.17	0.67	0.67	0.05	8.79	0.48	7.39	0.17	0.16	Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	0.01	0.01	Benzene
Insignificant Activities*	0.14	0.14	0.14	-	-	0.32	-	0.17	0.09	TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.43**	**83.88**	**13.95**	**63.03**	**61.92**	Ethylene Oxide
Roads	**2.26**	**0.45**	**0.11**	**-**	**-**	**-**	**-**	**-**	**-**	
Total PTE including fugitives	**3.41**	**1.74**	**1.40**	**4.88**	**37.43**	**83.88**	**13.95**	**63.03**	**61.92**	

This Significant Permit Revision includes the addtion of two (2) new sterilization chambers, with PTE of 24.04 tons per year of VOC and Ethylene Oxide (ETO)
*Insignificant Activity Emissions represent emissions from various assembly operations including gluing, package prep and printing.

Limited Potential To Emit of the Entire Source (tons/year)

Process / Emission Unit	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	Total HAPs	Single HAP	
Sterilization (S1 to S7)	-	-	-	-	-	9.42	-	9.42	9.42	ethylene oxide
Sterilization (S8 to S9)	-	-	-	-	-		-			
Surface Coating	-	-	-	-	-	2.05	-	0.01	0.01	Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	0.00	0.00	
Catheter Impregnation	-	-	-	-	-	4.04	-	0.75	0.75	Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	0.00	0.00	
Boilers	0.17	0.67	0.67	0.05	8.79	0.48	7.39	0.17	0.16	Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	0.01	0.01	Benzene
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	0.17	0.09	TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.43**	**31.38**	**13.95**	**10.53**	**9.42**	Ethylene Oxide
Roads	**2.26**	**0.45**	**0.11**	**-**	**-**	**-**	**-**	**-**	**-**	
Total PTE including fugitives	**3.41**	**1.74**	**1.40**	**4.88**	**37.43**	**31.38**	**13.95**	**10.53**	**9.42**	

Controlled Potential To Emit of the Entire Source (tons/year)

Process / Emission Unit	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	Total HAPs	Single HAP	
Sterilization (S1 to S7)	-	-	-	-	-	0.023	-	0.023	0.023	Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-	0.015	-	0.015	0.015	
Surface Coating	-	-	-	-	-	2.05	-	0.01	0.01	Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-			
Catheter Impregnation	-	-	-	-	-	4.04	-	0.75	0.75	Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-			
Boilers	0.17	0.67	0.67	0.05	8.79	0.48	7.39	0.17	0.16	Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	0.01	0.01	Benzene
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	0.17	0.09	TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.43**	**22.00**	**13.95**	**1.15**	**0.75**	Methanol
Roads	**2.26**	**0.45**	**0.11**	**-**	**-**	**-**	**-**	**-**	**-**	
Total PTE including fugitives	**3.41**	**1.74**	**1.40**	**4.88**	**37.43**	**22.00**	**13.95**	**1.15**	**0.75**	

Appendix A: Emissions Calculations
HAP Emissions Summary

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

HAP Emissions -Uncontrolled

Unit Number	Equipment Description	PTE (ton/yr)																	
		Acetaldehyde	Acrolein	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Methanol	Ethylene Oxide	Toluene	Xylene	Lead	Cadmium	Chromium	Manganese	Nickel	Total HAPs	Highest Single HAP	
	Sterilization (S1 to S7)								37.88								37.88	37.88	Ethylene Oxide
	Sterilization (S8 to S9)								24.04								24.04	24.04	
	Surface Coating							0.01									0.01	0.01	Methanol
	Miscellaneous Cleaning with IPA																0.00	0.00	
	Catheter Impregnation							0.75									0.75	0.75	Methanol
	Paclitaxel Treatment																	0.00	
	Boilers			0.00	1.06E-04	0.01	0.16			0.0003		4.40E-05	9.67E-05	1.23E-04	3.34E-05	1.85E-04	0.17	0.16	Hexane
	Emergency Diesel Generators	2.10E-04	6.58E-05	6.48E-03		6.59E-04				2.35E-03	1.61E-03						0.01	0.01	Xylene
	Insignificant Activities																0.17	0.09	TCE
	Total each HAP	2.10E-04	6.58E-05	6.67E-03	1.06E-04	0.01	0.16	0.76	61.92	2.65E-03	1.61E-03	4.40E-05	9.67E-05	1.23E-04	3.34E-05	1.85E-04	**63.02**	**61.92**	**Ethylene Oxide**

HAP Emissions -Limits

Unit Number	Equipment Description	PTE (ton/yr)																	
		Acetaldehyde	Acrolein	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Methanol	Ethylene Oxide	Toluene	Xylene	Lead	Cadmium	Chromium	Manganese	Nickel	Total HAPs	Highest Single HAP	
	Sterilization (S1 to S7)								9.42								9.42	9.42	Ethylene Oxide
	Sterilization (S8 to S9)																		
	Surface Coating							0.01									0.01	0.01	
	Miscellaneous Cleaning with IPA																0.00	0.00	
	Catheter Impregnation							0.75									0.75	0.75	Methanol
	Paclitaxel Treatment																	0.00	
	Boilers			0.01	4.37E-05	0.00	0.07			0.00012		1.82E-05	4.01E-05	5.10E-05	1.38E-05	7.65E-05	0.08	0.07	Hexane
	Emergency Diesel Generators	2.10E-04	6.58E-05	6.48E-03		6.59E-04				2.35E-03	1.61E-03						0.01	0.01	Xylene
	Insignificant Activities																0.17	0.09	TCE
	Total each HAP	2.10E-04	6.58E-05	1.30E-02	4.37E-05	0.00	0.07	0.76	9.42	2.47E-03	1.61E-03	1.82E-05	4.01E-05	5.10E-05	1.38E-05	7.65E-05	**10.44**	**9.42**	**Ethylene Oxide**

HAP Emissions - Controlled

Unit Number	Equipment Description	PTE (ton/yr)																	
		Acetaldehyde	Acrolein	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Methanol	Ethylene Oxide	Toluene	Xylene	Lead	Cadmium	Chromium	Manganese	Nickel	Total HAPs	Highest Single HAP	
	Sterilization (S1 to S7)								0.023								0.023	0.023	Ethylene Oxide
	Sterilization (S8 to S9)								0.015								0.015	0.015	Ethylene Oxide
	Surface Coating							0.01									0.01	0.01	
	Miscellaneous Cleaning with IPA																0.00	0.00	
	Catheter Impregnation							0.75									0.75	0.75	Methanol
	Paclitaxel Treatment																	0.00	
	Boilers			0.01	4.37E-05	0.00	0.07			0.00012		1.82E-05	4.01E-05	5.10E-05	1.38E-05	7.65E-05	0.08	0.07	Hexane
	Emergency Diesel Generators	2.10E-04	6.58E-05	6.48E-03		6.59E-04				2.35E-03	1.61E-03						0.01	0.01	Xylene
	Insignificant Activities																0.17	0.09	TCE
	Total each HAP	2.10E-04	6.58E-05	1.30E-02	4.37E-05	0.00	0.07	0.76	0.04	2.47E-03	1.61E-03	1.82E-05	4.01E-05	5.10E-05	1.38E-05	7.65E-05	**1.06**	**0.76**	**Methanl**

Appendix A: Emissions Calculations
Administrative Amendment Summary

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

Uncontrolled Potential To Emit of the Entire Source (tons/year)

Process / Emission Unit	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	Total HAPs	Single HAP
PTE Before Modification (S1-S7)						37.88		37.88	37.88
PTE After Modification (S1-S7)						37.88		37.88	37.88
PTE Increase	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*(0.00)*	*0.00*	*(0.00)*	*(0.00)*
PTE Before Modification (S8-S9)						24.04		24.04	24.04
PTE After Modification (S8-S9)						24.04		24.04	24.04
PTE Increase	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
Total Increase	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**(0.00)**	**0.00**	**(0.00)**	**(0.00)**

Controlled Potential To Emit of the Entire Source (tons/year)

Process / Emission Unit	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	Total HAPs	Single HAP
Before Modification (S1-S7)						0.46		0.46	0.46
After Modification (S1-S7)						0.02		0.02	0.02
Increase	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*(0.44)*	*0.00*	*(0.44)*	*(0.44)*
Before Modification (S8-S9)						0.29		0.29	0.29
After Modification (S8-S9)						0.02		0.02	0.02
Increase	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*-0.28*	*0.00*	*-0.28*	*-0.28*
Total Increase	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**(0.71)**	**0.00**	**(0.71)**	**(0.71)**

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100

Boilers

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

	Unit ID	MMBtu/hr
2018	UN1-HHW-B00	4.00
2018	UN1-HHW-B00	4.00
2018	UN1-HHW-B00	4.0000
	Total	12.00

Heat Input Capacity MMBtu/hr	HHV mmBtu/mmscf	Potential Throughput MMCF/yr
12.00	1020	103.1

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	7.6	0.6	100 **see below	5.5	84
Potential Emission in tons/yr	0.10	0.39	0.39	0.03	5.15	0.28	4.33

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.
PM2.5 emission factor is filterable and condensable PM2.5 combined.
**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

	HAPs - Organics				
	Benzene	Dichlorobenzene	Formaldehyd	Hexane	Toluene
Emission Factor in lb/MMcf	2.1E-03	1.2E-03	7.5E-02	1.8E+00	3.4E-03
Potential Emission in tons/yr	1.082E-04	6.184E-05	3.865E-03	9.275E-02	1.752E-04

	HAPs - Metals				
	Lead	Cadmium	Chromium	Manganese	Nickel
Emission Factor in lb/MMcf	5.0E-04	1.1E-03	1.4E-03	3.8E-04	2.1E-03
Potential Emission in tons/yr	2.576E-05	5.668E-05	7.214E-05	1.958E-05	1.082E-04

Total HAPs = 9.725E-02
Single HAP = 9.275E-02 Hexane

		Indirect Heating Units Which Began Operation After September 21, 1983				
Year Construction		Operating Capacity (MMBtu/hr)	Q (MMBtu/hr)	Calculated Pt (lb/MMBtu)	Particulate Limitation (Pt) (lb/MMBtu)	PM PTE based on AP-42 (lb/MMBtu)
2003	C241-F	2.1349	2.1349 + 2.1349 =	0.75	0.6	0.002
2003	C242-F	2.1349	4.27	0.75	0.6	0.002
2006	C230-F	1.68	4.2698 + 1.68 +1.68	0.63	0.6	0.002
2006	C231-F	1.68	+ 0.85 =	0.63	0.6	0.002
2006	C233-F	0.85	8.48	0.63	0.5	0.002
2018	EUN1-	4	8.4798 + 4.0 + 4.0 +	0.50	0.5	0.002
2018	EUN1-	4	4.0 =	0.50	0.5	0.002
2018	EUN1-	4	20.48	0.50	0.5	0.002

Where $Pt = 1.09/Q^{0.26}$

Pt = Pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input; and
Q = Total source maximum operating capacity rating in million Btu per hour (MMBtu/hr) heat input.

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100
Insignificant Combustion
Boilers
Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

Constructed	Unit ID	MMBtu/hr
2003	C241-F	2.1349
2003	C242-F	2.1349
2006	C230-F	1.68
2006	C231-F	1.68
2006	C233-F	0.85
		8.48

Heat Input Capacity MMBtu/hr	HHV mmBtu/mmscf	Potential Throughput MMCF/yr	
8.48	1020	72.8	7.647E-05

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	7.6	0.6	100 **see below	5.5	84
Potential Emission in tons/yr	0.07	0.28	0.28	0.02	3.64	0.20	3.06

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.
PM2.5 emission factor is filterable and condensable PM2.5 combined.
**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

	HAPs - Organics				
	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Toluene
Emission Factor in lb/MMcf	2.1E-03	1.2E-03	7.5E-02	1.8E+00	3.4E-03
Potential Emission in tons/yr	7.647E-05	4.370E-05	2.731E-03	6.554E-02	1.238E-04

	HAPs - Metals				
	Lead	Cadmium	Chromium	Manganese	Nickel
Emission Factor in lb/MMcf	5.0E-04	1.1E-03	1.4E-03	3.8E-04	2.1E-03
Potential Emission in tons/yr	1.821E-05	4.005E-05	5.098E-05	1.384E-05	7.647E-05

Total HAPs (tons/yr) = 6.872E-02
Single HAP (tons/yr) = 6.554E-02 Hexane

Methodology
All emission factors are based on normal firing.
MMBtu = 1,000,000 Btu
MMCF = 1,000,000 Cubic Feet of Gas
Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03
Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,020 MMBtu
Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton
The five highest organic and metal HAPs emission factors are provided above.
Additional HAPs emission factors are available in AP-42, Chapter 1.4.

Appendix A: Potential Emission Calculations
Source Wide Ethylene Oxide (EO) Emissions by Facility

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

Existing Sterilization Chamber (S1 through S7)	Stack Vent Identification #	Fraction of EO Usage	Uncontrolled VOC/HAP (lbs/yr) (1)	Uncontrolled VOC/HAP (tons/yr) (1)	Control Efficiency (%)	Controlled VOC/HAP (lbs/yr)	Controlled VOC/HAP (tons/yr)
Sterilization Chamber (Vacuum) Vents	RSV01	0.9504	72,000.0	36.0	99.99%	7.20	0.004
Sterilization Chamber Exhaust Vents (Back vents)	SV01	0.0034	260.0	0.1	99.00%	2.60	0.001
Product Transfer	See Notes[2]	0.0021	156.00	0.1	99.00%	1.56	0.001
Aeration (HC1 through HC14)	HV01	0.0441	3,340.0	1.7	99.00%	33.40	0.017
Total	-	1.00	75,756	37.88	-	44.76	0.023

Notes 73.37

(1) The Maximum Uncontrolled Emissions were calculated as follows: Potential Emissions = Fraction of EO Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]
(2) Pallet Transfer/Fugutives stack vents HV02, RV02, RV03, RV04 & RV05

The Maximum Production and Average EO/Pallet is confidential information, pursuant to 326 IAC 17.1-4

Potential Emissions for Sterilization Chambers S1 through S7 taken from FESOP Second Renewal No. F105-27381-00030, issued August 24, 2009. 0.990000

VOC and HAP = - ethylene oxide 0.9801

Proposed Revision (Units S8 and S9)	Stack Vent Identification #	Fraction of EO Usage	Uncontrolled VOC/HAP (lbs/yr) (1)	Uncontrolled VOC/HAP (tons/yr (1)	Control Efficiency (%)	Controlled VOC/HAP (lbs/yr)	Controlled VOC/HAP (tons/yr
Sterilization Chamber (Vacuum) Vents	RSV01	0.9500	45,671.0	22.8	99.99%	4.57	0.002
Sterilization Chamber Exhaust Vents (Back vents) (3)	SV02	0.0035	168.0	0.1	99.00%	1.68	0.001
Product Transfer	See Notes[2]	0.0021	101.0	0.1	99.00%	1.01	0.001
Aeration (HC1 through HC14)	HV01	0.0444	2,135.0	1.1	99.00%	21.35	0.011
Total	-	1.00	48,075.00	24.0	-	28.61	0.015

0.9999

Total 9 units	**61.92**		**0.038**

Notes

(1) The Maximum Uncon
(2) Pallet Transfer/Fugutives stack vents HV02, RV02, RV03, RV04 & RV05 Controlled Emissions were calculated as follows: Potential Emissions = Fraction of EO Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]

The Maximum Production and Average EO/Pallet is confidential information, pursuant to 326 IAC 17.1-4

(3) With this proposed revision, the new sterilization chambers S8 & S9 are not required to control the sterilization chamber exhaust vents (back vents), pursuant to 40 CFR 63, Subpart O (National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emissions Standards for Sterilization Facilities). The existing units, S1 through S7, are required to control the back vents pursuant to the source's 8-1-6 BACT for these units.

The size and production rate of these sterilization chambers is approved as confidential information, and was submitted to IDEM, OAQ with application on June 28, 2012.

Potential to Emit after Significant Permit Revision
Sterilization Chambers S1 through S9

	Uncontrolled Emissions	Controlled Emissions
Total (lbs/yr)	123,831.00	73.37
Total (tons/yr)	**61.92**	**0.038**

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Appendix A: Emission Calculations
VOC and Particulate
From Surface Coating, Miscellaneous Cleaning Operations, Catheter Inpregnation, and Paclitaxel Treatment

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

State Potential Emissions (uncontrolled):

Material (as applied)	Process	Density (Lb/Gal)	Weight % Volatile (H20& Organics)	Weight % Water	Weight % Organics	Volume % Water	Volume % Non-Vol (solids)	Maximum Gal of Mat. (gal/hr)	Pounds VOC per gallon of coating less water	Pounds VOC per gallon of coating	Potential VOC pounds per hour	Potential VOC pounds per day	Potential VOC tons per year	Particulate Potential ton/yr	lb VOC /gal solids	Transfer Efficiency
Surface Coating																
(Confidential)	Plastic Tubing & Metal Wiring	7.07	96.13%	0.00%	96.13%	0.00%	3.87%	0.033	7.7	7.66	0.25	6.07	1.11	0.00	197.90	100.00%
(Confidential)	Plastic Tubing	6.51	100.00%	0.00%	100.00%	0.00%	0.00%	0.003	6.5	6.51	0.21	5.16	0.94	0.00	N/A	100.00%
Miscellaneous Cleaning																
(Confidential)	Miscellaneous Cleaning	6.51	100.00%	0.00%	100.00%	0.00%	0.00%	0.332	6.5	6.51	2.16	51.87	9.47	0.00	N/A	100.00%
Catheter Impregnation																
(Confidential)	Catheter Impregnation	7.67	100.00%	0.00%	15.00%	0.00%	0.00%	0.144	1.2	1.20	0.17	4.13	0.75	0.00	N/A	100.00%
(Confidential)	Catheter Impregnation	8.82	100.00%	0.00%	85.00%	0.00%	0.00%	0.100	7.5	7.50	0.75	17.99	3.28	0.00	N/A	100.00%
Paclitaxel Treatment																
(Confidential)	Paclitaxel Treatment	6.60	100.00%	0.00%	100.00%	0.00%	0.00%	0.082	6.6	6.60	0.54	13.07	2.38	0.00	N/A	100.00%
(Confidential)	Paclitaxel Treatment	6.60	100.00%	0.00%	100.00%	0.00%	0.00%	0.082	6.6	6.60	0.54	13.07	2.38	0.00	N/A	100.00%
Total State Potential Emissions:											**4.64**	**111.35**	**20.32**	**0.00**		

Note:
Shaded boxes indicate information is confidential.

Methodology:
Pounds of VOC per Gallon Coating less Water = (Density (lb/gal) * Weight % Organics) / (1-Volume % water)
Pounds of VOC per Gallon Coating = (Density (lb/gal) * Weight % Organics)
Potential VOC Pounds per Hour = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr)
Potential VOC Pounds per Day = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (24 hr/day)
Potential VOC Tons per Year = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (8760 hr/yr) * (1 ton/2000 lbs)
Particulate Potential Tons per Year = (units/hour) * (gal/unit) * (lbs/gal) * (1- Weight % Volatiles) * (1-Transfer efficiency) *(8760 hrs/yr) *(1 ton/2000 lbs)
Pounds VOC per Gallon of Solids = (Density (lbs/gal) * Weight % organics) / (Volume % solids) * Transfer Efficiency
Total = Worst Coating + Sum of all solvents used
Controlled emission rate = uncontrolled emission rate * (1 - control efficiency)

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Appendix A: Emission Calculations
Uncontrolled Surface Coating HAP Emissions - Potential to Emit

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

Potential To Emit							
Material	Process	Density (lb/gal)	Maximum Gal of Mat. (gal/hr)	Weight % Methanol	Weight % MIBK	Methanol Emissions (tons/yr)	MIBK Emissions (tons/yr)
(Confidential)	Plastic Tubing & Metal Wiring	7.97	0.033	0.62%	0.31%	0.01	0.00
(Confidential)	Plastic Tubing	6.51	0.033	0.00%	0.00%	0.00	0.00
(Confidential)	Catheter Impregnation	7.97	0.144	15.00%	0.00%	0.75	0.00
						0.76	0.00
							0.76

Note:
Shaded boxes indicate information is confidential.

Methodology:
HAPs emission rate (tons/yr) = density (lb/gal) * (gal/unit) * (units/hour) * weight % HAP * % Flash Off * (8,760 hrs/yr) * (1 ton/2,000 lb)

Appendix A: Emission Calculations
Large Reciprocating Internal Combustion Engines - Diesel Fuel
Output Rating (>600 HP)
Maximum Input Rate (>4.2 MMBtu/hr)

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

Emissions calculated based on output rating (hp)

Output Horsepower Rating (hp)	4772.0
Maximum Hours Operated per Year	500
Potential Throughput (hp-hr/yr)	2,386,000
Sulfur Content (S) of Fuel (% by weight)	0.500

Emergency Diesel Generators:

Unit #1 (HP)	1850
Unit #2 (HP)	2922

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/hp-hr	7.00E-04	4.01E-04	4.01E-04	4.05E-03 *(.00809S)*	2.40E-02 **see below	7.05E-04	5.50E-03
Potential Emission in tons/yr	0.84	0.48	0.48	4.83	28.63	0.84	6.56

*PM10 emission factor in lb/hp-hr was calculated using the emission factor in lb/MMBtu and a brake specific fuel consumption of 7,000 Btu / hp-hr (AP-42 Table 3.3-1).
**NOx emission factor: uncontrolled = 0.024 lb/hp-hr, controlled by ignition timing retard = 0.013 lb/hp-hr

Hazardous Air Pollutants (HAPs)

	Pollutant						
	Benzene	Toluene	Xylene	Formaldehyde	Acetaldehyde	Acrolein	Total PAH HAPs***
Emission Factor in lb/hp-hr****	5.43E-06	1.97E-06	1.35E-06	5.52E-07	1.76E-07	5.52E-08	1.48E-06
Potential Emission in tons/yr	6.48E-03	2.35E-03	1.61E-03	6.59E-04	2.10E-04	6.58E-05	1.77E-03

***PAH = Polyaromatic Hydrocarbon (PAHs are considered HAPs, since they are considered Polycyclic Organic Matter)
****Emission factors in lb/hp-hr were calculated using emission factors in lb/MMBtu and a brake specific fuel consumption of 7,000 Btu / hp-hr (AP-42 Table 3.3-1).

Potential Emission of Total HAPs (tons/yr)	**1.31E-02**
gle HAP (benzene) (tons/yr) =	**6.48E-03**

Methodology
Emission Factors are from AP 42 (Supplement B 10/96) Tables 3.4-1 , 3.4-2, 3.4-3, and 3.4-4.
Potential Throughput (hp-hr/yr) = [Output Horsepower Rating (hp)] * [Maximum Hours Operated per Year]
Potential Emission (tons/yr) = [Potential Throughput (hp-hr/yr)] * [Emission Factor (lb/hp-hr)] / [2,000 lb/ton]

Appendix A: Emission Calculations
Other Insignificant Activities

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Renewal No.: 105-42357-00030
Reviewer: Jared Karban

The following emissions were calculated and approved with FESOP Second Renewal No. 105-27381-00030, issued August 24, 2009

Total Potential To Emit (tons/year)

Emissions Generating Activity				
Pollutant	Assembly Operations	Package Prep	Marking, Printing	**TOTAL**
PM	0.14	0.00	0.00	0.14
PM10/PM2.5	0.14	0.00	0.00	0.14
SO2	0.00	0.00	0.00	0.00
NOx	0.00	0.00	0.00	0.00
VOC	0.11	0.18	0.03	0.32
CO	0.00	0.00	0.00	0.00
total HAPs	0.00	0.17	0.00	0.17
worst case single HAP	0.00	0.09	0.00	0.09 TCE

Trichloroehylene = TCE

Appendix A: Emission Calculations
Fugitive Dust Emissions - Paved Roads

Company Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Permit Number: 105-42357-00030
Reviewer: Jared Karban

Paved Roads at Industrial Site
The following calculations determine the amount of emissions created by paved roads, based on 8,760 hours of use and AP-42, Ch 13.2.1 (1/2011).

Vehicle Informtation (provided by source)

Type	Maximum number of vehicles per day	Number of one-way trips per day per vehicle	Maximum trips per day (trip/day)	Maximum Weight of Loaded Vehicle (tons/trip)	Total Weight driven per day (ton/day)	Maximum one-way distance (feet/trip)	Maximum one-way distance (mi/trip)	Maximum one-way miles (miles/day)	Maximum one-way miles (miles/yr)
Vehicle (entering plant) (one-way trip)	14.0	1.0	14.0	17.0	238.0	1500	0.284	4.0	1451.7
Vehicle (leaving plant) (one-way trip)	14.0	1.0	14.0	20.0	280.0	1500	0.284	4.0	1451.7
		Totals	**28.0**		**518.0**			**8.0**	**2903.4**

Average Vehicle Weight Per Trip = 18.5 tons/trip
Average Miles Per Trip = 0.28 miles/trip

Unmitigated Emission Factor, Ef = [k * (sL)^0.91 * (W)^1.02] (Equation 1 from AP-42 13.2.1)

	PM	PM10	PM2.5	
where k =	0.011	0.0022	0.00054	lb/VMT = particle size multiplier (AP-42 Table 13.2.1-1)
W =	18.5	18.5	18.5	tons = average vehicle weight
sL =	9.7	9.7	9.7	g/m^2 = silt loading value for paved roads at iron and steel production facilities - Table 13.2.1-3)

Taking natural mitigation due to precipitation into consideration, Mitigated Emission Factor, Eext = E * [1 - (p/4N)] (Equation 2 from AP-42 13.2.1)
Mitigated Emission Factor, Eext = Ef * [1 - (p/4N)]
where p = 125 days of rain greater than or equal to 0.01 inches (see Fig. 13.2.1-2)
N = 365 days per year

	PM	PM10	PM2.5	
Unmitigated Emission Factor, Ef =	1.706	0.341	0.0837	lb/mile
Mitigated Emission Factor, Eext =	1.560	0.312	0.0766	lb/mile
Dust Control Efficiency =	50%	50%	50%	(pursuant to control measures outlined in fugitive dust control plan)

Process	Mitigated PTE of PM (Before Control) (tons/yr)	Mitigated PTE of PM10 (Before Control) (tons/yr)	Mitigated PTE of PM2.5 (Before Control) (tons/yr)
Vehicle (entering plant) (one-way trip)	1.13	0.23	0.06
Vehicle (leaving plant) (one-way trip)	1.13	0.23	0.06
Totals	**2.26**	**0.45**	**0.11**

Methodology
Total Weight driven per day (ton/day) = [Maximum Weight of Loaded Vehicle (tons/trip)] * [Maximum trips per day (trip/day)]
Maximum one-way distance (mi/trip) = [Maximum one-way distance (feet/trip) / [5280 ft/mile]
Maximum one-way miles (miles/day) = [Maximum trips per year (trip/day)] * [Maximum one-way distance (mi/trip)]
Average Vehicle Weight Per Trip (ton/trip) = SUM[Total Weight driven per day (ton/day)] / SUM[Maximum trips per day (trip/day)]
Average Miles Per Trip (miles/trip) = SUM[Maximum one-way miles (miles/day)] / SUM[Maximum trips per year (trip/day)]
Unmitigated PTE (tons/yr) = [Maximum one-way miles (miles/yr)] * [Unmitigated Emission Factor (lb/mile)] * (ton/2000 lbs)
Mitigated PTE (Before Control) (tons/yr) = [Maximum one-way miles (miles/yr)] * [Mitigated Emission Factor (lb/mile)] * (ton/2000 lbs)
Mitigated PTE (After Control) (tons/yr) = [Mitigated PTE (Before Control) (tons/yr)] * [1 - Dust Control Efficiency]

Abbreviations
PM = Particulate Matter
PM10 = Particulate Matter (<10 um)
PM2.5 = Particle Matter (<2.5 um)
PTE = Potential to Emit

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.
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Governor
Bruno L. Pigott
Commissioner

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TO: Shawn Adams
Cook Incorporated
PO Box 489
Bloomington, IN 47402-0489

DATE: March 6, 2020

FROM: Jenny Acker, Branch Chief
Permits Branch
Office of Air Quality

SUBJECT: Final Decision
FESOP Administrative Amendment
105-42357-00030

Enclosed is the final decision and supporting materials for the air permit application referenced above. Please note that this packet contains the original, signed, permit documents.

The final decision is being sent to you because our records indicate that you are the contact person for this application. However, if you are not the appropriate person within your company to receive this document, please forward it to the correct person.

A copy of the final decision and supporting materials has also been sent via standard mail to:
Derek Voskuil, Cook Incorporated
Simon Thomas, Atlantic Design Engineers

In addition, the Notice of Decision has been sent to the OAQ Permits Branch Interested Parties List.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178, or toll-free at 1-800-451-6027 (ext. 3-0178), and ask to speak to the permit reviewer who prepared the permit. If you think you have received this document in error, please contact Joanne Smiddie-Brush of my staff at 1-800-451-6027 (ext 3-0185), or via e-mail at jbrush@idem.IN.gov.

Mail Code 61-53

IDEM Staff	TAWEAVER 3/6/2020 Cook Incorporated 105-42357-00030 (final)		AFFIX STAMP HERE IF USED AS CERTIFICATE OF MAILING
Name and address of Sender	▶	Indiana Department of Environmental Management Office of Air Quality – Permits Branch 100 N. Senate Indianapolis, IN 46204	Type of Mail: **CERTIFICATE OF MAILING ONLY**

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1		Shawn Adams Cook Incorporated PO Box 489 Bloomington IN 474020489 (Source CAATS) Sent via USPS Certified Mail									
2		Derek Voskuil Cook Incorporated PO Box 489 Bloomington IN 474020489 *(RO CAATS)*									
3		Monroe County Health Department 119 W 7th St Bloomington IN 47404-3989 *(Health Department)*									
4		Mr. Richard Monday 545 E. Margaret Dr. Terre Haute IN 47801 *(Affected Party)*									
5		Monroe County Commissioners Monroe County Courthouse, Room 322 Bloomington IN 47404 *(Local Official)*									
6		Ellettsville Town Council PO Box 8, 221 N. Salle St. Ellettsville IN 47429 *(Local Official)*									
7		Simon Thomas Atlantic Design Engineers P.O. BOX 1051 Sandwich MA 02563 *(Consultant)*									
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